

12/6/99

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460OFFICE OF
PESTICIDES AND
TOXIC
SUBSTANCES

DEC - 6 1999

MEMORANDUM

Bar codes: D260843, D253952, D254316, D254075, D253660, D244061

SUBJECT: EFED's Section 3 Registration Eligibility Decision Chapter for Fipronil Use as Granular and Bait applications for control of Fire Ants and Other Turf pests (Revised)FROM: Edward Odenkirchen, Ph.D., Biologist
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TO: Ann Sibold, PM Team Reviewer 03
Registration Division

The Environmental Fate and Effects Division (EFED) has completed a revision of its review of potential ecological risks associated with a FIFRA Section 3 registration of fipronil as broadcast granular and bait applications for the control of fire ants and other turfgrass insect pests. This risk assessment evaluates the potential risks to birds, fish, and aquatic invertebrates and non-target insects associated with the above uses of fipronil. The revision reflect changes and additions to exposure calculations and risk characterization as a function with consultation with the registrant and review of a registrant rebuttal document.



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Fipronil
Environmental Fate and Ecological Effects
Assessment and Characterization
for a Section 3 for Broadcast Treatment with
Granular Product and Baits to Control Turf Insects and Fire Ants

EXECUTIVE SUMMARY

This risk assessment evaluates the potential risks to birds, fish, and aquatic invertebrates associated with the use of fipronil granular products as turf treatments for control of selected insect pests as well as mound and broadcast bait treatments for fire ant control. This assessment also addresses the registrant's rebuttal (Ortego, 1999 no MRID)¹ to the previously conducted risk assessment.

Drinking Water

No drinking water assessment for these turf uses was conducted. Based on application rates and the limitations of modeling for turf application scenarios, EFED believes that drinking water assessments for rice, cotton, and corn uses should be used for establishing drinking water exposure levels. For such detailed fate information, see the EFED risk assessments conducted for corn and rice wet-seed uses.

Avian and Mammalian Risks

This risk assessment indicates that, under the granular use scenarios investigated, there is a presumption of risk to avian species. Modeled exposures exceed the high acute risk for non-endangered bird species in the 20 g body weight class (examples may include but are not necessarily limited to young game birds and songbirds) for all granular application scenarios. These excursions above the acute high risk level of concern are less than an order of magnitude. There also is a presumption that granular formulations under maximum single and multiple applications pose risks to larger weight class birds (180 g with some upland game birds falling in this weight category as well as birds of other taxonomic orders), such that restricted use and/or endangered species levels of concern are triggered. Bait formulations, under the proposed use scenarios, do not appear to present exposure levels of fipronil that are above any avian risk levels of concern.

For all application scenarios, the risk quotients may be over-estimated because the small size of granules (and their attendant low mass of fipronil), as well as data on the low dislodgement of fipronil in turf grass studies suggest that avian exposures to fipronil may be lower than predicted by current EFED exposure modeling. Conversely, mixer/loader areas and equipment turn-about areas may exhibit higher granule deposition rates. Movement of granules into the thatch layer of treated fields can be expected to bring granules in proximity to target pests as well as non-target invertebrates that may be food for birds using treated fields. Therefore, absent more definitive testing of effects under actual use conditions, the confidence in risk predictions for these fipronil uses is low (actual risks maybe lower or higher in some areas).

¹Ortego, L.S. 1999. Fipronil: Response to EPA ecological risk assessment of broadcast granule for red imported fire ant control. Department of Toxicology and Ecotoxicology, Rhone-Poulenc Ag Company.

In addition, the EFED policy of using the most sensitive acute oral toxicity endpoint as the effects threshold for risk quotient calculation is uncertain in the case of fipronil. There are limited toxicity data that identify possible taxonomic differences in bird sensitivity, but additional toxicity testing or pharmacokinetic/dynamic studies would be needed to establish a definitive pattern of phylogenetic differences in sensitivity among bird species that would preclude using the most sensitive acute oral toxicity endpoint as the toxicity threshold.

Mammalian wildlife risks were not evaluated directly, but the lower acute toxicity of fipronil to mammals versus birds (rat LD₅₀ of 97 mg/kg versus bobwhite quail LD₅₀ of 11.3 mg/kg) suggests that equivalent exposures will result in risk quotients approximately 9-fold lower for mammals than birds. Because exposure estimation methods for birds and wild mammals are the same, fipronil levels protective of birds are expected to be protective of mammalian wildlife.

Aquatic Organism Risks

Tier I surface water modeling (GENEEC) results suggest no concern for risk to freshwater aquatic organisms. However there are concerns for acute and chronic effects in estuarine/marine invertebrates and concerns for chronic effects in estuarine/marine fish for fipronil and possibly (with uncertainty) for MB46513. The uncertainty in using the GENEEC modeling for estimating estuarine/marine exposure makes it difficult to claim a "high degree of certainty" for risk to estuarine and marine fish. Given the wide range of depths and flushing rates of estuaries, for instance, EFED cannot be sure whether values predicted by GENEEC are under-predictions or over-predictions of potential exposure.

The assessment suggests that terrestrial and aquatic endangered species may be at acute risk from use of fipronil granular formulations on turf grasses. EFED does not have sufficient geographical information on the specific areas of fipronil use (such are likely to be widespread) to determine if endangered species occur within the proposed sites of use.

Slit-application of granular formulations, as suggested on the Chipco® 61748A product label, would likely reduce the availability of granules although the degree to which slit application reduces surface granular residue is unknown. This would reduce potential avian exposure to granules. A possible risk mitigation for the protection of avian species would be to encourage the use of slit-application equipment for the control of mole crickets and the use of bait formulations for the control of fire ants and other ants.

USE PROFILE

Chemical Identification

The subject chemical of this risk assessment is identified by the trade chemical name fipronil. The chemical identification number is 129121. The Chemical Abstract System number is 061662.

Type of Use

Fipronil is an insecticide.

Site of Use

The proposed use sites include turf grass, including domestic lawns, sports fields, sod farms, commercial lawns, cemeteries, parks, recreational areas, and golf turf.

Target Pest

The target pests include fire ants, black and nuisance ants, mole crickets, fleas, and ticks.

Formulation Type

The labeled formulation of Fipronil proposed for registration on turf grass include:

1. H&G 61748A, a granule for broadcast treatment
2. Chipco® 61748A, a granule for broadcast treatment
3. Chipco® CHOICE™, a granule for broadcast treatment
4. Chipco® 61442A, a bait for broadcast and fire ant mound treatment

Rate and Timing of Application

H&G 61748A

The recommended application for H&G 61748A is 10 pounds of product per 5000 square feet. Using a labeled active ingredient concentration of 0.0143%, the fipronil application rate is 0.00143 lb a.i./5000 square feet or 0.0124 lb a.i./acre. There is no soil incorporation. Two applications per year are allowed according to the label for a maximum annual application of 0.0249 lb a.i./acre. No specific interval between applications are specified. However, the label does suggest that flea and tick control is provided for 30 days after application and fire ant control begins 7 to 14 days after initial treatment, with up to 4 weeks required for 100% control. The label states that applications may occur anytime between mid-March to mid-October.

Chipco® 61748A

The recommended application for Chipco® 61748A is 2 to 4 pounds of product per 1000 square feet. Using a labeled active ingredient concentration of 0.0143%, the Fipronil application rate is 0.000286 to 0.000572 lb a.i./1000 square feet or 0.0124 to 0.0249 lb a.i./acre. There is no soil incorporation of broadcast application, but slit treatment is a labeled option and the label recommends watering in of treatments for flea and tick control. Two applications per year are

allowed according to the label for a maximum annual application of 0.05 lb a.i./acre. No specific interval between applications is specified. However, the label does suggest that flea and tick control is provided for 30 days after application.

Chipco® CHOICE™

The recommended application for Chipco® CHOICE™ is 4.6 to 9.4 pounds of product per 1000 square feet. Using a labeled active ingredient concentration of 0.1%, the fipronil application rate is 0.0046 to 0.0094 lb a.i./1000 square feet or 0.0125 to 0.025 lb a.i./acre. There is no soil incorporation of broadcast application, but slit treatment is a labeled option. Two applications per year are allowed according to the label for a maximum annual application of 0.05 lb a.i./acre. No specific interval between applications is specified. However, the label does suggest that flea and tick control is provided for 30 days after application.

Chipco® 61442A

The recommended application for Chipco® 61442A is 1.5 to 15 pounds of product per acre for either broadcast or mound treatments. Using a labeled active ingredient concentration of 0.00015%, the fipronil application rate is 0.00000225 to 0.0000225 lb a.i./acre. There is no soil incorporation. Four applications per year are allowed according to the label for a maximum annual application of 0.000009 to 0.00009 lb a.i./acre. No specific interval between applications is specified. However, the label does suggest that flea and tick control is provided for 30 days after application. Fire ant control begins at 14 days after initial treatment, with up to 4 weeks required for 100% control.

TOXICOLOGICAL CHARACTERIZATION

The mechanism of toxicity of fipronil is through the gamma-amino butyric acid neurotransmission system, interfering with the chloride channel and subsequent interference of normal nervous function.

Toxicity to Birds

Tables 1, 2, and 3 summarize the available avian toxicity data for Fipronil and its predominate environmental degradates.

Table 4 presents the avian toxicological thresholds for fipronil and the photodegrade MB46513. The photodegrade was selected for evaluation in the avian risk assessment because the broadcast use of fipronil results in application of bait and granules above ground, which are subject to exposure to sunlight and therefore photodegradation. The selection of toxicity thresholds for this risk assessment concentrated on the acute avian single oral dose data, consistent with EFED methods for assessing risk for granular applications.

Toxicity to Aquatic Animals

Tables 5 through 8 present the aquatic organism toxicity data for Fipronil and degradates for freshwater and estuarine fish and invertebrates.

Table 9 presents the aquatic organism toxicity thresholds used in the assessment of risks to aquatic organisms. The table also presents the procedures to estimate toxicity endpoints for those degradates with no actual study information. The procedures generally involve using chronic:acute toxicity ratios relationships between freshwater organism toxicity endpoints for Fipronil and a particular degrade to modify existing toxicity data for the degrade or parent Fipronil. If there were insufficient data to make such comparisons, the degrade was assumed to be as toxic as parent Fipronil.

Toxicity to Non-Target Insects

Available data suggest that Fipronil is extremely toxic to honeybees via direct contact or oral ingestion of Fipronil residues with LD50 values of 0.00593 and 0.00417 $\mu\text{g ai/bee}$ for contact and oral exposures, respectively.

EXPOSURE ASSESSMENT

Avian Exposure Assessment

Birds may be exposed to granular pesticides by ingesting granules when foraging for food or grit. They also may be exposed by other routes, such as by walking on exposed granules, consuming prey contaminated by material released from granules, or drinking water contaminated by granules. The number of lethal doses (LD50s) that are available within one square foot immediately after application (LD50s/ft²) is used as the risk quotient for granular/bait products. Risk quotients are calculated for three separate weight classes of birds: 1000 g (e.g., waterfowl), 180 g (e.g., upland gamebird), and 20 g (e.g., songbird). It should be noted that the weight classes used for these calculations encompass different species of birds and provide information on exposures for different life stages of birds. Therefore, the lower weight classes are not limited to the example types of birds (upland game birds or songbirds) but may also reflect potential exposures to the young of bird species in larger weight classes. Furthermore, the exposures are not expressed in terms of granules per unit area, but as active ingredient per unit area as a means to consider the variety of potential exposure routes discussed above.

For the purposes of the risk assessment for granular formulations, three application rates were considered. The first is for a single minimum application of 0.000286 lb a.i./1000 square feet or 0.00000286 lb a.i./square foot. The second is for a maximum single application of 0.000572 lb a.i./1000 square feet or 0.00000572 lb a.i./square foot, this would also be equivalent to two minimum rate applications without any granule dissipation between applications. The third is the sum of two maximum applications, with no accounting for granule degradation, or 0.0000114 lb

a.i./square foot. Because nuisance ant and fire ant control does not require the watering-in process recommended for flea and tick control, watering-in was not considered quantitatively in the risk assessment. EFED currently does not have a method for assessing the impact of watering in of granules on avian exposure.

The assessment for bait formulations of Fipronil were based on a single application of 0.0000225 lb a.i./acre or 5.16×10^{-10} lb a.i./square foot. A second risk assessment exposure estimate for bait use was based on the sum of 4 applications at the single application rate, with no assumed Fipronil dissipation, for a total of 2.64×10^{-9} lb a.i./square foot.

Although the Fipronil soil photodegrade MB46513 is more acutely toxic than the parent compound (LD_{50} of 5 mg/kg versus 11.3 mg/kg in bobwhite quail), EFED currently does not have an exposure modeling method for estimating avian exposure to metabolites under granular application conditions. However, considering the low level of formation of this degrade in soil photodegradation studies (8% of applied parent compound), the absence of exposure modeling for this metabolite is not expected to greatly influence the conclusions of the risk assessment.

AQUATIC EXPOSURE ASSESSMENT

Tier 1 (GENEEC) surface water modeling was conducted for the turf grass application of granular and bait formulations of Fipronil. The minimum granular application scenario for surface water modeling was 0.0125 lb a.i./acre, two applications per year, yielding a maximum annual application of 0.025 lb ai/acre. The maximum granular application rate for surface water modeling was 0.025 lb a.i./acre, with two applications per year yielding a maximum annual application of 0.05 lb a.i./acre. No soil incorporation was assumed. The application interval for both scenarios was set at 7 days, the minimum period post treatment that pest control may be observed. The maximum bait application rate for surface water modeling was 0.0000225 lb a.i./acre, with four applications per year yielding a maximum annual application of 0.00009 lb a.i./acre. No soil incorporation was assumed. The application interval was conservatively set at 14 days, the minimum period post treatment that pest control may be observed.

Table 10 summarizes the input parameters for GENEEC modeling. Table 11 summarizes the estimated surface water concentrations for Fipronil and degradates for each application scenario. Application rates (and subsequent estimated water concentrations) for degradates are based on maximum degrade residues from laboratory studies as fraction of applied parent material.

DRINKING WATER ASSESSMENT

A drinking water assessment for these turf uses was not conducted. Based on application rates and the limitations of modeling for turf application scenarios, it is believed that drinking water assessments for rice, cotton, and corn uses should be used for establishing drinking water exposure levels.

RISK ASSESSMENT and CHARACTERIZATION

Risk Quotient (RQ) and the Levels of Concern (LOC)

Risk characterization integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects. The means of this integration is called the quotient method. Risk quotients (RQs) are calculated by dividing acute and chronic exposure estimates by toxicity values.

$$RQ = \text{EXPOSURE/TOXICITY}$$

RQs are then compared to OPP's levels of concern (LOCs). These LOCs are used by OPP to assess potential risk to nontarget organisms and the need to consider regulatory action. The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on nontarget organisms. LOCs currently address the following risk presumption categories: (1) acute high -- potential for acute risk is high; regulatory action may be warranted in addition to restricted use classification, (2) acute restricted use -- the potential for acute risk is high, but may be mitigated through restricted use classification, (3) acute endangered species - endangered species may be adversely affected if actual exposure occurs, and (4) chronic risk - the potential for chronic risk is high, regulatory action may be warranted. Currently, EFED does not perform assessments for chronic risk to plants, acute or chronic risks to nontarget insects, or chronic risk from granular/bait formulations to birds or mammals.

The ecotoxicity test values (measurement endpoints) used in the acute and chronic risk quotients are derived from required studies. Examples of ecotoxicity values derived from short-term laboratory studies that assess acute effects are: (1) LC50 (fish and birds), (2) LD50 (birds and mammals), (3) EC50 (aquatic plants and aquatic invertebrates) and (4) EC25 (terrestrial plants). Examples of toxicity test effect levels derived from the results of long-term laboratory studies that assess chronic exposure-related effects are: (1) LOAEC (birds, fish, and aquatic invertebrates) and (2) NOAEC (birds, fish and aquatic invertebrates). For birds and mammals, the NOAEC generally is used as the ecotoxicity test value in assessing chronic exposure risks, although other values may be used when justified. Generally, the NOAEC is used as the ecotoxicity test value in assessing chronic exposure risks to fish and aquatic invertebrates.

Risk presumptions and the corresponding RQs and LOCs, are tabulated below.

Risk Presumptions for Terrestrial Animals

Risk Presumption	RQ	LOC
<u>Birds</u>		
Acute High Risk	EEC/LC50 or LD50/sqft ² or LD50/day ³	0.5
Acute Restricted Use	EEC/LC50 or LD50/sqft or LD50/day (or LD50 < 50 mg/kg)	0.2

Risk Presumptions for Terrestrial Animals

Risk Presumption	RQ	LOC
Acute Endangered Species	EEC/LC50 or LD50/sqft or LD50/day	0.1
Chronic Risk	EEC/NOEC	1

¹ abbreviation for Estimated Environmental Concentration (ppm) on avian/mammalian food items

² $\frac{\text{mg/ft}^2}{\text{LD50} * \text{wt. of bird}}$ ³ $\frac{\text{mg of toxicant consumed/day}}{\text{LD50} * \text{wt. of bird}}$

Risk Presumptions for Aquatic Animals

Risk Presumption	RQ	LOC
Acute High Risk	EEC ¹ /LC50 or EC50	0.5
Acute Restricted Use	EEC/LC50 or EC50	0.1
Acute Endangered Species	EEC/LC50 or EC50	0.05
Chronic Risk	EEC/MATC or NOEC	1

¹ EEC = (ppm or ppb) in water

Risk Assessment for Birds

The acute risk quotients for broadcast applications of granular and bait formulations are listed in Table 12. Under an assumption of minimum single application rate, no acute risk Levels of Concern (LOCs) are exceeded for birds in any weight category. For the maximum single application rate of granular formulation, and for the sum of two minimum applications, all the EFED acute risk LOCs are exceeded for 20 g birds, and the endangered species LOC are exceeded for 180 gram birds. Under the application scenario for two maximum applications of granular Fipronil the acute high risk, restrictive use, and endangered species LOCs are exceeded for 20 g birds; and the restricted use and endangered species levels of concern are exceeded for 180 g birds.

No acute LOCs are exceeded by any bait formulation application scenario for Fipronil.

Currently, EFED has no risk assessment methodology for evaluating the potential for risks to birds from long-term exposure via the ingestion and contact with granular formulations. This remains a considerable uncertainty with respect to fipronil, considering the stability of the parent material and a number of its toxic degradates.

Risk to Aquatic Animals

Tables 13 through 15 present the calculations of acute and chronic risk quotients for aquatic organisms.

Under the minimum application scenario modeled for granular formulations (two applications at 0.0125 lb a.i./acre, with a 7-day interval), no acute nor chronic risk levels of concern are exceeded for any freshwater aquatic organisms. However, predicted water concentrations of fipronil, MB46136, and MB46513 exceed the acute toxicity thresholds established for estuarine/marine invertebrates at levels high enough to trigger the EFED acute high risk LOC (MB45950 exceeds the endangered species acute level of concern). The EFED chronic exposure LOC is exceeded for estuarine invertebrates for fipronil and all degradates excepting MB45950. Estuarine/marine fish chronic levels of concern are only exceeded by MB46513 concentrations. Refer to the risk characterization for discussion of the implications of assumptions of degrade formation rates and other uncertainties on these risk conclusions.

Under the maximum granular application scenario, only MB46513 exceeds any freshwater organism level of concern, and that is a slight excursion over the acute endangered species fish level of concern. However, predicted water concentrations of fipronil, MB46136, and MB46513 exceed the acute toxicity thresholds established for estuarine/marine invertebrates at levels high enough to exceed the EFED acute high risk LOC (MB45950 exceeds the restricted acute level of concern). Estimated water concentrations of Fipronil and all degradates are high enough to result in risk quotients that exceed the chronic risk LOC for estuarine/marine invertebrates. The EFED chronic exposure LOC is exceeded for estuarine/marine fish for Fipronil MB46513. No estuarine/marine fish RQs are high enough to trigger concern for fipronil nor any degradates. Refer to the risk characterization for discussion of the implications of assumptions of degrade formation rates and other uncertainties on risk conclusions.

The aquatic organism risk quotients for application of bait formulations of Fipronil do not exceed any acute or chronic LOCs.

Risks to Non-Target Insects

EFED currently does not have a quantitative method for assessing risks to non-target insects. Given its high toxicity to insects such as honey bees, application of Fipronil to turf grass areas is likely to impact non-target insects (effects are implied by data on honey bees but non-target insects are not limited to bees). It should be noted that such impacts may not occur solely as a result of contact with dislodgeable residues on plant surfaces, but may also be the result of exposure via similar routes as are efficacious for controlling target insect pests.

Endangered Species

Assessment of potential risks to avian endangered species is limited by the receptor species selection process incorporated into this risk assessment. Direct application of the risk quotients calculated for avian receptors should be limited to endangered species of similar body weights and dietary habits. To this end, the calculated risk quotients suggest a potential for acute and chronic risks to endangered avian species that may utilize turf grass areas.

Aquatic EECs suggest that minimum and maximum application scenarios for granular Fipronil formulations have the potential to result in surface water concentrations of Fipronil and some degradates at levels high enough to pose an acute and chronic risk to endangered species, should exposure occur.

The proposed use sites for Fipronil granular and bait formulations addressed in this risk assessment include domestic lawns, sports fields, sod farms, commercial lawns, cemeteries, parks, recreational areas, and golf turf. These areas are likely to be widely distributed across the country and the types of pests proposed for control by the formulations are also likely to be widely distributed. Consequently, EFED does not have sufficient resolution on potential use site locations to pinpoint geographic overlap with known occurrence of terrestrial or aquatic endangered species. EFED is aware that the Florida scrub jay and the Nashville crayfish are endangered species associated with some proposed use sites under the granular and bait formulation labels addressed in this risk assessment (personal communication, Larry Turner, USEPA/OPP/FEAD).

Risk Characterization

Avian Risk Characterization

The assessment suggests that proposed application of granular pesticide is sufficient to trigger acute high risk concerns for small birds (ca. 20 g in body weight) under all application scenarios modeled. The RQs exceed the level of concern ($RQ = 0.5$) by factors ranging from 1.1x to 4.5x. A single application at maximum rate or two applications at the lowest recommended application rate triggers the endangered species concern for birds under the 180 g exposure model with an RQ exceeding the endangered species LOC of 0.1 by a factor of 1.2x. Two applications at the maximum rate result in sufficient pesticide release to exceed the acute restricted use level of concern (0.2) by a factor of 1.1x under the exposure model scenario for 180 g birds. No levels of concern were triggered for birds with body weights of 1000 g. It is likely that birds approximated by the 180 and 20 g exposure models are prevalent in a variety of habitat types in proximity to turf use sites for Fipronil.

Uncertainties with respect to toxicological sensitivity and body size

The registrant's rebuttal (Ortego, 1999) to the previous version of this risk assessment maintains that the use of the most sensitive acute lethal toxicity endpoint (LD_{50} 11.3 mg/kg for the bobwhite quail) is not appropriate for the 20 g bird category. The rebuttal suggests that gallinaceous birds (such as quail) are much more sensitive than passeriform birds said to be represented by the 20 g bird category in EFED exposure assessments. The rebuttal contends that the available house sparrow toxicity data should be the threshold against which 20 g bird exposures are compared.

It is factual to state that the available data for three tested gallinaceous birds (bobwhite quail,

taxonomic orders not included the available toxicity data set) that could be expected to occur in the proposed treatment areas.

With respect to uncertainty related to interspecies sensitivity and appropriate body size matching between toxicity testing species and birds in the wild, EFED concludes the following:

1. There is insufficient toxicological evidence at present (either from acute testing or pharmacological bases) to definitively demonstrate a phylogenetically-influenced pattern of toxicological sensitivity that is conserved for all species within and between bird orders that may be represented by birds on the proposed use sites for fipronil granular applications.
2. The EFED use of the most sensitive tested species LD₅₀ (northern bobwhite quail) for the avian risk assessment is appropriate because (a) body weights of early life stages of the species are encompassed by the 20 g exposure scenario employed in the risk assessment and (b) it has not been demonstrated that the large number of untested bird species potentially on use sites are of less sensitivity to fipronil than bobwhites.

Uncertainty associated with a requirement for granular consumption and availability of granules

Ortego (1999) contends that birds on treated areas would have to consume a large number of granules in order to receive dosages at levels of acute concern. EFED has performed a similar analysis that suggests a 20 g bird would have to be exposed to the fipronil in 1,580 mg of granules (1105 actual granules) to attain an LD₅₀ from the 0.0143% granular formulations:

fraction of granular product that is a.i.: 0.000143
weight of granules: 1.4 mg (information on granule from Ortego, 1999)
small bird body weight - 0.02 kg
LD₅₀: 11.3 mg a.i./kg
LD₅₀ per bird: 11.3 mg a.i./kg X 0.02 kg = 0.226 mg a.i./bird
LD₅₀ mg granular product/bird: 0.226 mg a.i./bird / 0.000143 = 1580 mg granules/bird
LD₅₀ in granules/bird: 1580 mg granules/bird / 1.43 mg = 1105 granules/bird

Because the high risk threshold is half the LD₅₀, a 20 g bird would have to be exposed to compound from 553 granules to exceed the high risk acute concern level.

For the 0.1% a.i. granular formulation the equations are as follows:

fraction of granular product that is a.i.: 0.001
weight of granules: 0.17 mg (information on granule from Ortego, 1999)
small bird body weight - 0.02 kg
LD₅₀: 11.3 mg a.i./kg

LD₅₀ per bird: 11.3 mg a.i./kg X 0.02 kg = 0.226 mg a.i./bird
LD₅₀ mg granular product/bird: 0.226 mg a.i./bird / 0.001 = 226 mg granules/bird
LD₅₀ in granules/songbird: 226 mg granules/songbird / 0.17 mg = 1329 granules/bird

Because the high risk threshold is half the LD₅₀, a 20 g bird would have to be exposed to compound from 665 granules to exceed the high risk acute concern level.

An initial reaction (as presented in Ortego 1999) to such information might be that actual oral ingestion consumption of a very large number of granules is **required** for such avian exposures. This is not entirely accurate. The risk index of LD₅₀s per square foot was intended to evaluate the effects implications of the amount of available **toxicant**, not necessarily the number of granules available on a per square foot basis (Felthousen 1977)³. Indeed, the routes of exposure may include direct ingestion of granules mistaken for grit or food, incidental consumption of granules associated with food sources, ingestion of compound that is absorbed by food sources, compound dissolved in surface water puddles serving as drinking water sources, compound/granules incidentally consumed during preening, and dermal absorption of compound through contact with granules or pesticide desorbed from granules. The individual contributions of each route of exposure are not quantified using the present methodology, and so the relative contributions of each remain uncertain. However, in the case of fipronil, some of these routes (e.g., accumulation in soil biota and subsequent ingestion) are theoretically less significant than direct granular ingestion.

The registrant has provided a study of dislodgeable fipronil residues from turf (MRID 44506901) in an effort to demonstrate that granular fipronil is minimally available to birds in a turf application scenario. The study involved media wipe and roll over media sample collection methods. The first involves the use of cloth-covered platform shoes to sample a plot and the other uses a 25-pound cloth covered roller rolled over the turf surface. These techniques were intended to mimic exposures from dislodgeable residue picked up on skin, clothing and shoes. The results of this sampling showed minimal dislodgeable residues collected on the sampling devices, including actual granules. The registrant maintains that the fipronil granules were in the thatch layer of the turf and so not available to biota. EFED agrees that the granules may be in the thatch layer, but it should be understood that the invertebrate pest organisms and other non-target invertebrates that are the likely food sources for birds feeding on turf also are in the thatch layer. It is therefore reasonable to expect that birds will feed in the thatch layer. In addition, the dislodgement of residues from granules or turf grasses to drinking water sources (guttation and puddled precipitation) are not evaluated by this study. The assumption of potential bioavailability of granules is not refuted by the available data from this study, but the data do suggest that direct exposure to granules could be more limited than indicated by an assumption of 100% availability.

The assessment does not consider higher exposures in areas of mixer/loader operations or at turn-

³Felthousen, R. 1977. Classification of granulated formulations. (Memorandum from R. Felthousen to Environmental Safety Section, September 9, 1977).

around areas for application equipment operation.

Absent actual testing of avian exposure and effects in the field, it is not possible to quantify the impacts of small granule size, movement of granules to the thatch layer, and potential for higher localized deposition of granules at sites of mixer/loaders and equipment turn-about on the actual toxic risks of fipronil granules to birds. Therefore the overall confidence of the avian risk quotients for these fipronil uses is low.

Uncertainty associated with degradation of fipronil

Degradation of fipronil following granule application granules was not considered in this assessment and likely results in overestimation of exposure for multiple applications if granule degradation is rapid. The registrant has conducted a field dissipation study of granular applications of fipronil and reported parent fipronil half-lives on the order of 0.5 months (MRID 43291705). However the study was complicated by "rainfall and/or irrigation in excess of the historical or that needed for good agronomics", thereby limiting its predictive utility under normal irrigation/precipitation regimes. Still, the use of a half-life of 0.5 months (assumed equivalent to 14 days) could reduce predicted fipronil levels upon a second application to to 85% of the levels estimated in the risk assessment. This reduction would not materially change the RQs to levels below levels of concern. Furthermore, the assessment for avian risks does not consider risks from chronic exposure to fipronil residues in soil, nor does it consider acute and chronic risks from fipronil degradates, which in total, had a much longer half-life than parent fipronil (EFED-approved methods for estimating chronic exposure scenarios for granular pesticides are not currently available).

Aquatic Organism Risk Assessment

Risks predicted for fipronil and degradates in this assessment are based on surface water concentrations of the compounds as approximated under the closed pond system assumed under the GENEEC model. No dilution effects in lotic receiving waters have been factored into the assessment. EFED does not have sufficient specific information of the hydrology of such systems in proximity to the variety of turf use sites for fipronil granules and baits to determine such dilution effects. There is also uncertainty in using the GENEEC modeling for estimating estuarine/marine exposure, which makes it difficult to claim a "high degree of certainty" for risks to estuarine and marine fish. Given the wide range of depths and flushing rates of estuaries, for instance, EFED cannot be sure whether values predicted by GENEEC are under-predictions or over-predictions of potential exposure.

The registrant has indicated that the exposure characterization for the photodegrade MB46513 may be over-estimated. The registrant contends that using the aqueous photolysis study-based conversion of fipronil to the photodegrade (43%) is higher than a more appropriate soil photolysis conversion rate of 8%. While EFED believes that the aqueous photolysis will take place in receiving waters, a quick assessment of the impact of assuming an 8% conversion factor

yields RQ values for estuarine fish and invertebrates approximately 5-fold lower than the current assessment. It should be recognized that even with this 5-fold reduction in MB46513 residues in water, the LOCs for chronic effects in estuarine aquatic organisms would still be exceeded, but acute estuarine/marine invertebrate and fish concerns would be reduced below levels of concern.

EFED has assumed that parent fipronil is stable in aerobic aquatic environments. However, the registrant has submitted aerobic aquatic metabolism data showing the half-life of fipronil can range from 15 days (US study) vs 22 to 35 days (EU data). A preliminary review of the EU studies suggests the existence of a stratified redox condition between the water and sediment, which limits interpretation of the "aerobic" aquatic degradation. EFED conducted some GENEEC modeling to bound the EECs (emphasis on 56-day EEC) with regard to the aerobic aquatic metabolism half-life. EFED modeled systems using 15 days and 45 days (3*15 days to approximate an upper bound value from these data) as representative half-lives. The resulting EECs for parent fipronil are as follows:

Half-Life	Total Rate	Peak	21 day	56 day
			-----µg/L-----	
15 days	0.025 lbs/A	0.387	0.177	0.077
15 days	0.050 lbs/A	0.774	0.354	0.154
45 days	0.025 lbs/A	0.387	0.221	0.111
45 days	0.050 lbs/A	0.774	0.442	0.223

The 15-day half-life results for the 21-day and 56-day EECs reflect reductions in estimated concentrations in surface water (compared to those used in risk quotient calculations) of 29% and 45% respectively. The 45-day half-life results for the 21-day and 56-day EECs reflect reductions of 12% and 22% when compared to EECs used in calculating RQs. Incorporation of either of these half-life values (15-day or 45-day) would not eliminate concerns for estuarine invertebrate risks, because the chronic RQs would still exceed the LOC by factors ranging from 25x to 71x. However, incorporation of these degradation rates would reduce the chronic estuarine fish RQ for parent fipronil below the level of concern.

LABELING AND POTENTIAL FOR MITIGATION

if a decision is made to grant a registration for these fipronil uses, EFED believes that the following label language may help mitigate effects to non-target organisms.

The label for H&G 61748A should include the following information:

This pesticide is toxic to birds, fish, and aquatic invertebrates. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Cover, incorporate, or clean up granules that are spilled. Do not contaminate water when disposing of equipment wash water or

rinsate.

The labels for Chipco® 61748A and CHOICE™ suggest that the formulations can be applied by slit-application equipment. This equipment would reduce the above-ground proportion of granules and thereby reduce the potential exposure of birds to these granules. An incorporation efficiency of as little as 90% would reduce exposures by an order of magnitude and therefore reduce potential risks below acute high risk levels of concern. While slit-application is useful for mole crickets, it is not indicated on the label as an effective treatment method for fire ants and other insect pests on the proposed granular labels. However, bait formulations for fire ant control are of lower risk to avian and aquatic organisms and steps to encourage their use in place of granule applications would reduce terrestrial and aquatic wildlife exposures to fipronil associated with the chemical's use to control fire ants.

Table 1. Avian Single Oral Dose Toxicity Data for Fipronil and Degradates

Species	Chemical	%A.I.	LD50 mg/kg	MRID	Classification
Northern bobwhite	fipronil	96	11.3	42918617	core
Mallard	fipronil	96.8	>2150	42918616	core
Pigeon	fipronil	97.7	>500	42918613	supplemental
Red-legged partridge	fipronil	95.4	34	42918614	supplemental
Pheasant	fipronil	95.4	31	42918615	supplemental
House sparrow	fipronil	96.7	1000	42918618	supplemental
Northern bobwhite	MB46513	99.7	5	43776601	supplemental
Mallard duck	MB46513	98.6	420	43776602	supplemental
Northern bobwhite	fipronil (1.6 WG)	1.6	1065	42918619	supplemental

Table 2. Avian Subacute Dietary Toxicity for Fipronil

Species	Chemical	%A.I.	LC50 mg/kg-diet	MRID	Classification
Northern bobwhite	fipronil	95	48	42918620	core
Mallard duck	fipronil	95	>5000	42918621	core

Table 3. Avian Reproductive Toxicity for Fipronil

Species	Chemical	%A.I.	LOEC mg/kg-diet	NOEC mg/kg-diet	MRID	Classification
Northern bobwhite	fipronil	96.7	>10	10	42918622	supplemental
Mallard duck	fipronil	96.7	>1000	1000	42918623	core

Table 4. Avian Toxicity Thresholds Used in the Fipronil Fire Ant/Turf Pest Risk Assessment

Chemical	Acute Toxicity Threshold mg/kg	Acute Threshold Origin
Fipronil	11.3	1
MB46513	5	1

1 most sensitive species tested

Table 5. Fish Acute Toxicity for Fipronil and Degradates

Species	Chemical	%A.I.	LC50 ug/L	MRID	Classification
Bluegill sunfish	fipronil	100	83	42918624	core
Rainbow trout	fipronil	100	246	42977902	core
Rainbow trout	MB46136	99.2	39	42918673	supplemental
Bluegill sunfish	MB46136	99.2	25	42918674	supplemental
Bluegill sunfish	MB46513	no data	20	DPR 157298	
Rainbow trout	MB46513	94.7	>100,000	43291718	supplemental
Rainbow trout	MB46513	100	>100,000	43279703	core
Sheepshead minnow	fipronil	96.1	130	43291702	core

Table 6. Fish Chronic Exposure Toxicity for Fipronil

Species	Chemical	%A.I.	LOEL ug/L	NOEL ug/L	Effect	MRID	Classification
Rainbow trout	fipronil	96.7	15	6.6	larval length	42918627	core
Sheepshead minnow	fipronil	97	0.41	0.24	length, weight	44605502	core

Table 7. Aquatic Invertebrate Acute Toxicity for Fipronil and Degradates

Species	Chemical	%A.I.	EC50 ug/L	MRID	Classification
<i>Daphnia magna</i>	fipronil	100	190	42918625	core
<i>Daphnia magna</i>	RPA 10461	94.7	100,000	43291719	supplemental
<i>Daphnia magna</i>	MB46136	100	29	42918671	supplemental
<i>Daphnia magna</i>	MB46950	100	100	42918669	supplemental
<i>Crassostrea virginica</i>	fipronil	96.1	770	43291701	core
<i>Mysidopsis bahia</i>	fipronil	96.1	0.14	43279701	core

Table 8. Aquatic Invertebrate Chronic Exposure Toxicity for Fipronil and Degradates

Species	Chemical	%A.I.	LOEL ug/L	NOEL ug/L	Effect	MRID	Classification
<i>Daphnia magna</i>	fipronil	100	20	9.8	length	42918626	supplemental
<i>Mysidopsis bahia</i>	fipronil	97.7	0.005	none	survival, growth, reproduction	43681201	supplemental
<i>Daphnia magna</i>	MB46513	no data	100	41	growth	DPR 15730	no DER
<i>Daphnia magna</i>	MB46136	no data	1.5	0.63	weight	DPR 15730	no DER
<i>Daphnia magna</i>	MB46950	no data	22	13	reproduction, growth	DPR 15730	no DER

DPR - California Department of Pesticide Regulation Study Number - Note: these studies not reviewed by EPA

Table 9. Aquatic Organism Toxicity Thresholds Used in the Fipronil Fire Ant/Turf Pest Risk Assessment

Chemical	Acute Toxicity Threshold ug/L	Chronic Toxicity Threshold ug/L	Acute Threshold Origin	Chronic Threshold Origin
Freshwater Fish				
Fipronil	83	6.6	1	1
MB46136	25	2.0	1	2
MB46513	20	1.6	1	2
MB45950	83	6.6	3	3
Freshwater Invertebrates				
Fipronil	190	9.8	1	1
MB46136	29	0.63	1	1
MB46513	190	41	3	1
MB45950	100	13	1	1
Estuarine Fish				
Fipronil	130	0.24	1	1
MB46136	39	0.07	4	5
MB46513	31	0.06	4	5
MB45950	130	0.24	3	3
Estuarine Invertebrates				
Fipronil	0.14	0.005	1	1
MB46136	0.02	0.0003	6	7
MB46513	0.14	0.005	3	3
MB45950	0.07	0.007	6	7

1 most sensitive species tested

2 most sensitive species tested acute value Xmultiplied by chronic:acute ratio of parent fipronil

3 assumed to be equivalent to parent fipronil

4 parent fipronil acute value multiplied by metabolite:parent fipronil ratio for freshwater fish acute values

5 parent fipronil chronic value multiplied by metabolite:parent fipronil ratio for freshwater fish acute values

6 acute freshwater metabolite value multiplied by acute estuarine:acute freshwater ratio for parent fipronil

7 chronic freshwater for metabolite multiplied by chronic estuarine:chronic freshwater ratio for parent fipronil

Table 10. GENEEC Model Input Parameters for Fipronil and Degradates

Parameter	Fipronil	MB 46136	MB 46513	MB 45950
Mean Koc (mL/g)	727	4208	1290	3911
Aerobic Soil Metabolism Half-life (days)	128	700	693	700
Aqueous Photolysis Half-life (days)	0.16	7	Stable*	Stable
Hydrolysis Half-life	Stable	Stable	Stable	Stable
Aerobic Aquatic Metabolism Half-life	Stable	Stable	Stable	Stable
Water Solubility (mg/L)	2.4	0.16	0.95	0.1
Application Rates (lbs a.i./acre) **				
granular minimum	0.0125	0.003	0.005375	0.000625
granular maximum	0.025	0.006	0.01075	0.00125
bait maximum	2.25E-05	5.4E-06	9.675E-06	1.125E-06
Number of Applications				
granular	2	2	2	2
bait	4	4	4	4
Application Interval (days)				
granular	7	7	7	7
bait	14	14	14	14

* stable fate inputs are assigned value of 0 in GENEEC model

** application rates for degradates are based on parent application rate multiplied by fate study fractions of formation (MB46136 24%, MB46513 43%, MB45950 5%)

Table 11. Water Concentrations of Fipronil and Degradates

Chemical	Peak Water Concentration (ug/L)	21-day Average Water Concentration (ug/L)	56-day Average Water Concentration (ug/L)
Granular Minimum Application Rate 0.0125 lb a.i./acre X 2			
Fipronil	3.87E-01	2.50E-01	1.41E-01
MB46136	2.58E-02	1.53E-02	1.03E-02
MB46513	1.12E-01	9.22E-02	7.04E-02
MB45950	5.65E-03	3.49E-03	2.38E-03
Granular Maximum Application Rate 0.025 lb a.i./acre X 2			
Fipronil	7.74E-01	5.01E-01	2.83E-01
MB46136	5.15E-02	3.07E-02	2.05E-02
MB46513	2.24E-01	1.84E-01	1.48E-01
MB45950	1.13E-02	6.98E-03	4.76E-03
Bait Maximum Application Rate 2.25 E-05 lb a.i./acre X 2			
Fipronil	1.27E-03	8.20E-04	4.60E-04
MB46136	9.00E-05	6.00E-05	4.00E-05
MB46513	4.00E-04	3.30E-04	2.70E-04
MB45950	3.00E-05	2.00E-05	1.00E-05

Table 12. Avian Risk Quotient Calculations for Fipronil

Exposure Scenario	Bird Mass (g)	Most Sensitive Avian Species LD50 (mg/kg)	Total Dose Normalized for Bird Weight (mg)	Application Rate (lb /square foot)	Application Rate (mg/square foot)	Acute RQ
Fipronil						
Granular formulation (single minimum application)	1000	11.3	11.30	2.86E-07	1.30E-01	0.011
	180		2.03			0.064
	20		0.23			0.573
Granular formulation (single maximum application)	1000	11.3	11.30	5.72E-07	2.59E-01	0.023
	180		2.03			0.127
	20		0.23			1.146
Granular formulation (two maximum applications)	1000	11.3	11.30	1.14E-06	5.18E-01	0.046
	180		2.03			0.255
	20		0.23			2.292
Bait formulation (single maximum application)	1000	11.3	11.30	5.16E-10	2.34E-04	0.00002
	180		2.03			0.00012
	20		0.23			0.001
Bait formulation (four maximum applications)	1000	11.3	11.30	2.64E-09	1.20E-03	0.0001
	180		2.03			0.001
	20		0.23			0.005

Risk Presumption	LOC
Acute High Risk	0.5
Acute Restricted Use	0.2
Acute Endangered Species	0.1
Chronic Risk	1

Table 13. Aquatic Organism Risk Quotient Calculations for Fipronil and Degradates Under Minimum Granular Application Rate Scenario

Chemical	Acute Toxicity Threshold (ug/L)	Chronic Toxicity Threshold (ug/L)	Peak Water Concentration (ug/L)	Acute RQ	21-day Average Water Concentration (ug/L)	56-day Average Water Concentration (ug/L)	Chronic RQ
Freshwater Fish							
Fipronil	83	6.6	3.87E-01	0.0046627		1.41E-01	0.02
MB46136	25	2.0	2.58E-02	0.001032		1.03E-02	0.01
MB46513	20	1.6	1.12E-01	0.0056		7.04E-02	0.04
MB45950	83	6.6	5.65E-03	6.807E-05		2.38E-03	0.00
Freshwater Invertebrates							
Fipronil	190	9.8	3.87E-01	0.0020368	2.50E-01		0.03
MB46136	29	0.63	2.58E-02	0.0008897	1.53E-02		0.02
MB46513	190	41	1.12E-01	0.0005895	9.22E-02		0.00
MB45950	100	13	5.65E-03	5.65E-05	3.49E-03		0.00
Estuarine Fish							
Fipronil	130	0.24	3.87E-01	0.0029769		1.41E-01	0.59
MB46136	39	0.07	2.58E-02	0.0006589		1.03E-02	0.14
MB46513	31	0.06	1.12E-01	0.0035754		7.04E-02	1.22
MB45950	130	0.24	5.65E-03	4.346E-05		2.38E-03	0.01
Estuarine Invertebrates							
Fipronil	0.14	0.005	3.87E-01	2.7642857	2.50E-01		50.00
MB46136	0.02	0.0003	2.58E-02	1.2073892	1.53E-02		47.60
MB46513	0.14	0.005	1.12E-01	0.8	9.22E-02		18.44
MB45950	0.07	0.007	5.65E-03	0.0766786	3.49E-03		0.53

Risk Presumption	LOC
Acute High Risk	0.5
Acute Restricted Use	0.1
Acute Endangered Species	0.05
Chronic Risk	1

Table 14. Aquatic Organism Risk Quotient Calculations for Fipronil and Degradates Under Maximum Granular Application Rate Scenario

Chemical	Acute Toxicity Threshold (ug/L)	Chronic Toxicity Threshold (ug/L)	Peak Water Concentration (ug/L)	Acute RQ	21-day Average Water Concentration (ug/L)	56-day Average Water Concentration (ug/L)	Chronic RQ
Freshwater Fish							
Fipronil	83	6.6	7.74E-01	0.009325		2.83E-01	0.04
MB46136	25	2.0	5.15E-02	0.00206		2.05E-02	0.01
MB46513	20	1.6	2.24E-01	0.0112		1.48E-01	0.09
MB45950	83	6.6	1.13E-02	0.000136		4.76E-03	0.00
Freshwater Invertebrates							
Fipronil	190	9.8	7.74E-01	0.004074	5.01E-01		0.05
MB46136	29	0.63	5.15E-02	0.001776	3.07E-02		0.05
MB46513	190	41	2.24E-01	0.001179	1.84E-01		0.00
MB45950	100	13	1.13E-02	0.000113	6.98E-03		0.00
Estuarine Fish							
Fipronil	130	0.24	7.74E-01	0.005954		2.83E-01	1.18
MB46136	39	0.07	5.15E-02	0.001315		2.05E-02	0.28
MB46513	31	0.06	2.24E-01	0.007151		1.48E-01	2.56
MB45950	130	0.24	1.13E-02	8.7E-05		4.76E-03	0.02
Estuarine Invertebrates							
Fipronil	0.14	0.005	7.74E-01	5.528571	5.01E-01		100.20
MB46136	0.02	0.0003	5.15E-02	2.410099	3.07E-02		95.51
MB46513	0.14	0.005	2.24E-01	1.6	1.84E-01		36.80
MB45950	0.07	0.007	1.13E-02	0.153357	6.98E-03		1.05

Risk Presumption	LOC
Acute High Risk	0.5
Acute Restricted Use	0.1
Acute Endangered Species	0.05
Chronic Risk	1

Table 15. Aquatic Organism Risk Quotient Calculations for Fipronil and Degradates Under Bait Application Rate Scenario

Chemical	Acute Toxicity Threshold ug/L	Chronic Toxicity Threshold ug/L	Peak Water Concentration ug/L	Acute RQ	21-day Average Water Concentration ug/L	56-day Average Water Concentration ug/L	Chronic RQ
Freshwater Fish							
Fipronil	83	6.6	1.27E-03	1.5E-05		4.60E-04	0.00007
MB46136	25	2.0	9.00E-05	3.6E-06		4.00E-05	0.00002
MB46513	20	1.6	4.00E-04	2E-05		2.70E-04	0.00017
MB45950	83	6.6	3.00E-05	3.6E-07		1.00E-05	0.000002
Freshwater Invertebrates							
Fipronil	190	9.8	1.27E-03	6.7E-06	8.20E-04		0.00008
MB46136	29	0.63	9.00E-05	3.1E-06	6.00E-05		0.00010
MB46513	190	41	4.00E-04	2.1E-06	3.30E-04		0.00001
MB45950	100	13	3.00E-05	3E-07	2.00E-05		0.000002
Estuarine Fish							
Fipronil	130	0.24	1.27E-03	9.8E-06		4.60E-04	0.00192
MB46136	39	0.07	9.00E-05	2.3E-06		4.00E-05	0.00055
MB46513	31	0.06	4.00E-04	1.3E-05		2.70E-04	0.00467
MB45950	130	0.24	3.00E-05	2.3E-07		1.00E-05	0.00004
Estuarine Invertebrates							
Fipronil	0.14	0.005	1.27E-03	0.00907	8.20E-04		0.16400
MB46136	0.02	0.0003	9.00E-05	0.00421	6.00E-05		0.18667
MB46513	0.14	0.005	4.00E-04	0.00286	3.30E-04		0.06600
MB45950	0.07	0.007	3.00E-05	0.00041	2.00E-05		0.00302

Risk Presumption	LOC
Acute High Risk	0.5
Acute Restricted Use	0.1
Acute Endangered Species	0.05
Chronic Risk	1